

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

Correction: The Notice of Final Rulemaking originally published at 8 A.A.R. 3194, August 2, 2002 for 3 A.A.C. 1 (Department of Agriculture - Administration) was published with the incorrect effective date. The correct effective date is July 10, 2002.

Correction: The Notice of Final Rulemaking originally published at 8 A.A.R. 3241, August 2, 2002 for 17 A.A.C. 4 (Department of Transportation - Title, Registration, and Driver Licenses) was published with the incorrect effective date. The correct effective date is July 12, 2002.

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TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSURE

PREAMBLE

1. Sections Affected

R9-10-101
R9-10-102
R9-10-103
R9-10-104
R9-10-105
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Rulemaking Action

New Section
Repeal
New Section
Repeal
Repeal
Repeal
Repeal
Repeal
Repeal
Repeal
Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-132(A) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-405, 36-406, 36-407, 36-421, 36-422, 36-424, 36-425, and 41-1073

3. The effective date of the rules:

August 1, 2002

4. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 655, February 15, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 702, February 22, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Kathleen Phillips, Rules Administrator

Address: Department of Health Services
1740 W. Adams, Suite 102
Phoenix, AZ 85007

Telephone: (602) 542-1264

Fax: (602) 364-1150

E-mail: kphilli@hs.state.az.us

or

Name: Mary Wiley, Assistant Director

Address: Department of Health Services
Assurance and Licensure Services
1647 E. Morten, Suite 220
Phoenix, AZ 85020

Telephone: (602) 674-4200

Fax: (602) 861-0645

E-mail: mwiley@hs.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rule:

A.R.S. § 36-405(A) requires the Director of the Department of Health Services to adopt rules necessary for establishing minimum standards and requirements for the construction, modification, and licensure of health care institutions necessary to assure public health, safety, and welfare. A.R.S. § 36-405(B) grants the Director the authority to classify and subclassify health care institutions according to character, size, range of services provided and standard of patient care required for the purposes of licensure. A.R.S. § 36-421 requires an applicant for an initial health care institution license to submit architectural plans and specifications with an initial application. A.R.S. § 36-422 sets forth application requirements for health care institutions.

The rules in 9 A.A.C. 10, Article 1, adopted effective February 4, 1981, set forth the legal authority, intent, and purpose of the Article in addition to definitions applicable to the Chapter, health care institution classes and subclasses, and requirements for documentation, transfers, general licensure, and initial and renewal applications. The rules do not comply with the requirements for licensing time-frames in A.R.S. §§ 41-1072 through 41-1079 or current rule-making format and style requirements and contain passive, outdated, ambiguous, and nonspecific language.

In addition, subsequent to the adoption of 9 A.A.C. 10, Article 1, the authorizing statutes were amended in 1983, 1985, 1986, 1987, 1988, 1989, 1990, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, and 2001. Consequently, there are discrepancies between the authorizing statutes and the rules. There are no provisions in the current rules implementing the requirements in A.R.S. § 36-421, which combines the permit process and the initial license application process; A.R.S. § 36-424(C), which requires the Director to accept a copy of a health care institution's accreditation report in lieu of all licensing inspections; and A.R.S. § 36-425(B), which allows a license to be valid for up to two years if the health care institution has no deficiencies during a renewal licensing inspection. The rules are also inconsistent with A.R.S. § 36-422(F), which allows a single group license for an accredited hospital that includes accredited facilities located separately from the main hospital building, and A.R.S. § 36-422(G), which allows a single license for a county-operated accredited hospital when the county's population is more than one million, including the single license accredited facilities located separately from the main hospital.

The Department is promulgating rules that are consistent with statutory requirements including licensing time-frames, comply with current rulemaking format and style requirements, and reflect current industry practice and Department policy.

The Department issues health care institution licenses to facilities that are located across the state, have a wide range of licensed capacities, provide a variety of services, and serve diverse populations. The licensing time-frames established in the rules allow for the onsite inspection of facilities taking into consideration the diversity and complexity of the facilities and the time required for enforcement action that may be necessary during the licensure process.

7. A reference to any study that the agency relied on and its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rules benefit the Department and impose substantial one-time costs and substantial ongoing annual costs upon the Department. The rules benefit the Department by establishing clear, current, and accurate information and by conforming to statute and the Department's current practice. Implementing time-frame rules will impose substantial initial one-time costs upon the Department of approximately \$21,620. These initial one-time costs include staff training, review and revision of the Department's license applications, and the development and installation of computer software to track compliance with license time-frame rules. Implementing time-frame rules will also impose substantial annual ongoing costs upon the Department which, the Department estimates, will be approximately \$15,734 each year. The annual ongoing costs include date entry, tracking and monitoring data, generating letters of administrative completeness, and generating and analyzing reports.

The rules should not benefit or cost a political subdivision of this state.

The rules benefit business, specifically the operators of the approximately 2,300 health care institutions that are impacted by the rule. The clear, current, and accurate information contained in the rules may reduce business transaction costs that include time contacting the Department to obtain current and accurate information. While the savings in transaction costs to each individual provider may be minimal, the collective savings that may be realized across all 2,300 health care institutions that are impacted by the rule could be substantial.

The rules impose substantial costs upon the Department and may impact public employment if the Department requires additional staff to implement the rules.

The impact of the rules upon small business, as defined in A.R.S. § 41-1001(19), is the same as the impact on business, described above. However, the rule does not require an assisted living home to submit architectural plans and specifications, which are typically developed by a professional architect. Instead, an assisted living home is required to submit a site plan and a floor plan in lieu of architectural plans and specifications from a professional architect. Assisted living homes serve 10 or fewer individuals, are typically in private neighborhoods, and are almost always a small business. While the requirements for an architectural drawing review are appropriate for large health care institutions, those requirements are not appropriate for small homes in private neighborhoods.

The rules do not directly cost or benefit private persons or consumers. Private persons or consumers may indirectly benefit from the rules if transaction cost savings realized by operators of health care institutions are passed along to consumers as lower health care costs.

The rules may impact state revenues if the Department requires additional state funds to implement time-frame rules. State revenues may also be impacted if the Department fails to comply with time-frame requirements and is required by state law to refund licensing fees.

Providing clear, current, and accurate information on the content of applications for a health care institution license, conforming rules to statute and current Department practice, and complying with statutory time-frame requirements is, the Department believes, the least costly and intrusive method of achieving the purpose of the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

In addition to technical and grammatical changes made at the suggestion of G.R.R.C. staff, the following changes were made.

R9-10-101

Added a definition for "adjacent". Renumber subsequent definitions.

In the definition of "license" added "one or more" and deleted "subclass or behavioral health services agency".

In the definition of "substantial" in subsection (53) added "A change in the health care institution's licensed capacity" for clarification.

R9-10-103

Added "Except for R9-10-122, this Article does not apply to a behavioral health service agency regulated under 9 A.A.C. 20" to clarify the applicability of the Article to behavioral health service agency.

Amended subsection (C) to read "The Department does not require a separate health care institution license for".

Amended subsection (C)(2) as follows:

A facility operated by a licensed health care institution that is:

- a. Adjacent to the licensed health care institution; or
- b. Not adjacent to the licensed health care institution but is connected to the licensed health care institution by an all-weather enclosure that is:

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- i. Owned by the health care institution, or
- ii. Leased by the health care institution with exclusive rights of possession.

R9-10-104

Amended subsection (A)(2) to read “If the health care institution is located on land under the jurisdiction of a local governmental agency, one of the following:” to clarify applicability of the rule.

Added “issued by the local governmental agency” to subsection (A)(2)(b) for clarification.

Amended subsection (A)(5)(a) as follows:

- a. If the health care institution is located on land under the jurisdiction of a local governmental agency, one of the following provided by the local governmental agency:
 - i. A copy of the Certificate of Occupancy,
 - ii. Documentation that the facility was approved for occupancy, or
 - iii. Documentation that a certificate of occupancy for the facility is not available.

R9-10-105(A)(2)

Added “and exclusive rights of possession of the leased facility” to clarify requirement.

R9-10-105(A)(4)

Changed “by” to “under” to clarify applicability.

R9-105(A)(5)(b)

Changed “The requested licensed capacity for the health care institution” to “The licensed capacity requested by the applicant for the health care institution” for clarification.

R9-10-105(D)

Because R9-10-103(A) was added for clarification of the applicability of this Article to behavioral health service agencies, this subsection was redundant and was deleted.

R9-10-107(A)(2)

Added “and exclusive rights of possession of the leased facility” to clarify requirement.

R9-10-107(F)

Because R9-10-103(A) was added for clarification of the applicability of this Article to behavioral health service agencies, this subsection was redundant and was deleted.

R9-10-108(B)(4)

Changed “120 days” to “180 days” to allow an applicant additional time to submit missing documents or information.

Changed (C)(2) to (B)(2) in two places to correct cross-reference.

R9-10-108(C)(4)

Changed (D)(4) or (D)(5) to (C)(5) to correct cross-reference.

R9-10-108(C)(5)(a)

Added “For an initial health care institution application” to clarify applicability.

Changed (D)(2) to (C)(2) to correct cross-reference.

Table

Changed the overall time-frame for approval of architectural plans and specifications from 160 days to 105 days.
Changed the administrative completeness time-frame from 100 days to 45 days.

Changed the overall time-frame for health care institution initial and renewal licenses from 180 days to 120 days.
Changed the substantive review time-frame from 150 days to 90 days.

For an approval of a change to a health care institution license, changed the administrative completeness time-frame from 60 days to 15 days and the substantive review time-frame from 15 days to 60 days.

R9-10-109(C)

Deleted the phrase “Except as provided in subsection (D)”.

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R9-10-109(D)

Changed to read:

A governing authority is not required to submit documentation of a health care institution's architectural plans and specifications required in R9-10-105(A)(5) if:

1. The health care institution has not ceased operations for more than 30 days,
2. A modification has not been made to the health care institution,
3. The services the health care institution is authorized by the Department to provide are not changed, and
4. The location of the health care institution's premises is not changed.

11. A summary of the principal comments and the agency response to them:

R9-10-101

COMMENT

Define the term "agricultural land".

DEPARTMENT'S REPSONSE

Because the requirement only applies to agricultural land using pesticides regulated under A.R.S. § 3-365, the Department did not add a definition of "agricultural land" but did change "by" to "under" in R9-10-105(A)(4) for clarification.

COMMENT

Define the term "bed".

DEPARTMENT'S RESPONSE

The Department did not add a definition for the term "bed" because the term "bed" would duplicate the terms "inpatient bed" and "licensed capacity" defined in statute and used in the rules.

COMMENT

The terms "modification" and "construction" are not clear.

DEPARTMENT'S REPSONSE

The terms are defined in statute and the Department cannot modify statutory definition by rule. The term "substantial" is used in the statutory definition of "modification" and the Department has defined "substantial" in rule for clarification.

R9-10-104(A)(1)(d)

COMMENT

The Department should not require the governing authority or licensee to sign a statement regarding the compliance of the architectural plans and specifications.

DEPARTMENT'S RESPONSE

Although the architect is responsible for preparing architectural plans and specifications and ensuring that a health care institution's architectural plans and specifications comply with applicable requirements as prescribed in A.R.S. Title 32, Article 1, the governing authority and licensee are submitting the application for the Department's approval of the health care institution's architectural plans and specifications and are ultimately responsible for ensuring that the architectural plans and specifications comply with applicable requirements.

R9-10-104(A)(2) and (A)(5)

COMMENT

There are health care institutions that are not under the jurisdiction of a local governmental agency and cannot obtain a building permit or a certificate of occupancy.

DEPARTMENT'S RESPONSE

The Department agrees and amended the rule to clarify the requirement for health care institutions located on land under the jurisdiction of a local governmental agency.

R9-10-104(A)(5)

COMMENT

Sometimes a certificate of occupancy is not available for a facility previously built.

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DEPARTMENT'S RESPONSE

The Department agrees and amended the rule to allow an applicant or licensee to submit documentation that is available to demonstrate that a facility was approved for occupancy.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their locations in the rules:

Not applicable

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSURE

ARTICLE 1. GENERAL

Section

- R9-10-101. ~~Reserved~~ Definitions
- R9-10-102. ~~Reserved~~ Health Care Institution Classes and Subclasses; Requirements
- R9-10-103. ~~Reserved~~ Licensure Exceptions
- R9-10-104. ~~Reserved~~ Approval of Architectural Plans and Specifications
- R9-10-105. ~~Reserved~~ Initial License Application
- R9-10-107. ~~Reserved~~ Renewal License
- R9-10-108. ~~Reserved~~ Time-frames
- R9-10-109. ~~Reserved~~ Changes Affecting a License
- R9-10-110. ~~Reserved~~ Enforcement Actions
- R9-10-111. ~~Legal authority~~ Denial, Revocation, or Suspension of License
- R9-10-112. ~~Intent and purpose of this Article~~ Repealed
- R9-10-113. ~~Definitions~~ Repealed
- R9-10-114. ~~Classifications~~ Repealed
- R9-10-116. ~~Documentation~~ Repealed
- R9-10-117. ~~Transfer to another subclass~~ Repealed
- R9-10-121. ~~General requirements for licensure~~ Repealed
- R9-10-123. ~~Initial application~~ Repealed
- R9-10-124. ~~Renewal application~~ Repealed

ARTICLE 1. GENERAL

R9-10-101. ~~Reserved~~ Definitions

In addition to the definitions in A.R.S. § 36-401(A), the following definitions apply in this Chapter unless otherwise specified:

1. "Accredited" means accredited by a nationally recognized accreditation organization.
2. "Administrative completeness review time-frame" means the number of days from agency receipt of an application for a license until the agency determines that the application contains all components required by statute or rule, including all information required to be submitted by other government agencies. The administrative completeness review time-frame does not include the period of time during which an agency provides public notice of the license application or performs a substantive review of the application.
3. "Adjacent" means not intersected by:
 - a. Property owned or operated by a person other than the applicant or licensee, or
 - b. A public thoroughfare.
4. "Administrative office" means a location used by personnel for recordkeeping and record retention but not for providing medical services, nursing services, or health-related services.
5. "Adult day health care facility" means a facility providing adult day health services during a portion of a continuous twenty-four hour period for compensation on a regular basis for five or more adults not related to the proprietor.
6. "Applicant" means a governing authority requesting:
 - a. Approval of architectural plans and specifications of a health care institution.
 - b. Licensure of a health care institution, or

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- c. A change in a health care institution's license.
7. "Application packet" means the information, documents, and fees required by the Department for the:
- a. Approval of a health care institution's modification or construction, or
- b. Licensure of a health care institution.
8. "Assisted living center" means an assisted living facility that provides resident rooms or residential units to eleven or more residents.
9. "Assisted living facility" means a residential care institution, including adult foster care, that provides or contracts to provide supervisory care services, personal care services or directed care services on a continuing basis.
10. "Behavioral health service agency" has the same meaning as "agency" in A.A.C. R9-20-101.
11. "Certification" means a written statement that an item or a system complies with the applicable requirements incorporated by reference in R9-1-412.
12. "Certified health physicist" means an individual recognized by the American Board of Health Physics as complying with the health physics criteria and examination requirements established by the American Board of Health Physics.
13. "Change in ownership" means conveyance of the ability to appoint, elect, or otherwise designate a health care institution's governing authority from an owner of the health care institution to another person.
14. "Chief administrative officer" means an individual designated by a governing authority to implement the governing authority's direction in a health care institution.
15. "Contractor" has the same meaning as in A.R.S. § 32-1101.
16. "Construction" means the building, erection, fabrication, or installation of a health care institution.
17. "Day" means calendar day.
18. "Department" means the Arizona Department of Health Services.
19. "Directed care services" means programs and services, including personal care services, provided to persons who are incapable of recognizing danger, summoning assistance, expressing need or making basic care decisions.
20. "Equipment" means an apparatus, a device, a machine, or a unit that is required to comply with the specifications incorporated by reference in R9-1-412.
21. "Facilities" means buildings used by a health care institution for providing any of the types of services as defined in A.R.S. Title 36, Chapter 4.
22. "Factory-built building" has the same meaning as in A.R.S. § 41-2142.
23. "Governing authority" means the individual, agency, group or corporation, appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the health care institution are vested.
24. "Health care institution" means every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, health screening services, other health-related services, supervisory care services, personal care services or directed care services and includes home health agencies as defined in A.R.S. § 36-151 and hospice service agencies.
25. "Health-related services" means services, other than medical, pertaining to general supervision, protective, preventive and personal care services, supervisory care services or directed care services.
26. "Home health agency" means an agency or organization, or a subdivision of such an agency or organization, which meets all of the following requirements:
- a. Is primarily engaged in providing skilled nursing services and other therapeutic services.
- b. Has policies, established by a group of professional personnel, associated with the agency or organization, including one or more physicians and one or more registered professional nurses, to govern the services referred to in subdivision (a), which it provides, and provides for supervision of such services by a physician or registered professional nurse.
- c. Maintains clinical records on all patients.
27. "Hospice" means a hospice service agency or the provision of hospice services in an inpatient facility.
28. "Hospital" has the same meaning as in 9 A.A.C. 10, Article 2.
29. "Inpatient beds" or "resident beds" means accommodations with supporting services, such as food, laundry and housekeeping, for patients or residents who generally stay in excess of twenty-four hours.
30. "Leased facility" means a facility occupied or used during a set time in exchange for compensation.
31. "License" means:
- a. Written approval issued by the Department to a person to operate a class or subclass of a health care institution, except for a behavioral health service agency, at a specific location;
- b. Written approval issued by the Department to a person to operate one or more behavioral health service agency subclasses at a specific location; or
- c. Written approval issued to an individual to practice a profession in this state.
32. "Licensee" means an owner approved by the Department to operate a health care institution.
33. "Medical services" means the services pertaining to medical care that are performed at the direction of a physician on behalf of patients by physicians, dentists, nurses and other professional and technical personnel.

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34. “Mobile clinic” means a movable structure that:
 - a. Is not physically attached to a health care institution’s facility.
 - b. Provides outpatient medical services under the direction of the health care institution’s personnel, and
 - c. Is not intended to remain in one location indefinitely.
35. “Modification” means the substantial improvement, enlargement, reduction, alteration of or other change in a health care institution.
36. “Nursing care institution” means a health care institution providing inpatient beds or resident beds and nursing services to persons who need nursing services on a continuing basis but who do not require hospital care or direct daily care from a physician.
37. “Nursing services” means those services pertaining to the curative, restorative and preventive aspects of nursing care that are performed at the direction of a physician by or under the supervision of a registered nurse licensed in this state.
38. “Outpatient surgical center” means a type of health care institution with facilities and limited hospital services for the diagnosis or treatment of patients by surgery whose recovery, in the concurring opinions of the surgeon and the anesthesiologist, does not require inpatient care in a hospital.
39. “Outpatient treatment center” means a health care institution class without inpatient beds that provides medical services for the diagnosis and treatment of patients.
40. “Overall time-frame” means the number of days after receipt of an application for a license during which an agency determines whether to grant or deny a license. The overall time-frame consists of both the administrative completeness review time-frame and the substantive review time-frame.
41. “Owner” means a person who appoints, elects, or designates a health care institution’s governing authority.
42. “Patient” means an individual receiving medical services, nursing services, or health-related services from a health care institution.
43. “Person” has the same meaning as in A.R.S. § 1-215 and includes a governmental agency.
44. “Personal care services” means assistance with activities of daily living that can be performed by persons without professional skills or professional training and includes the coordination or provision of intermittent nursing services and the administration of medications and treatments by a nurse who is licensed pursuant to Title 32, Chapter 15 or as otherwise provided by law.
45. “Personnel” means, except as defined in specific Articles in this Chapter or 9 A.A.C. 20, an individual providing medical services, nursing services, or health-related services to a patient.
46. “Premises” means property that is licensed by the Department as part of the health care institution where medical services, nursing services, or health-related services are provided to a patient.
47. “Project” means specific construction or modification of a facility stated on an architectural plans and specifications approval application.
48. “Provisional license” means the Department’s written approval to operate a health care institution issued to an applicant or licensee that is not in substantial compliance with the applicable laws and rules for the health care institution.
49. “Recovery care center” means a health care institution or subdivision of a health care institution that provides medical and nursing services limited to recovery care services.
50. “Residential care institution” means a health care institution other than a hospital or a nursing care institution which provides resident beds or residential units, supervisory care services, personal care service, directed care services or health-related services for persons who do not need inpatient nursing care.
51. “Room” means space contained by walls from and including the floor to ceiling with at least one door.
52. “Satellite facility” means an outpatient facility at which the hospital provides outpatient medical services.
53. “Substantial” when used in connection with a modification means:
 - a. An addition or deletion of an inpatient bed or a change in the use of one or more of the inpatient beds;
 - b. A change in a health care institution’s licensed capacity;
 - c. A change in the physical plant, including facilities or equipment, that costs more than \$300,000; or
 - d. A change in a health care institution that affects compliance with applicable physical plant codes and standards incorporated by reference in R9-1-412.
54. “Substantial compliance” means that the nature or number of violations revealed by any type of inspection or investigation of a licensed health care institution does not pose a direct risk to the life, health or safety of patients or residents.
55. “Substantive review time-frame” means the number of days after the completion of the administrative completeness review time-frame during which an agency determines whether an application or applicant for a license meets all substantive criteria required by statute or rule. Any public notice and hearings required by law shall fall within the substantive review time-frame.
56. “Swimming pool” has the same meaning as “semipublic swimming pool” in A.A.C. R18-5-201.
57. “System” means interrelated, interacting, or interdependent elements forming a whole.

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- 58. “Tax ID number” means a numeric identifier that a person uses to report financial information to the United States Internal Revenue Services.
- 59. “Treatment” means a procedure or method to cure, improve, or palliate an injury, an illness, or a disease.
- 60. “Unclassified health care institution” means a health care institution not classified or subclassified in statute or in rule that provides medical services, nursing services, or health-related services.

R9-10-102. ~~Reserved~~ Health Care Institution Classes and Subclasses; Requirements

- A.** A person may apply for a license as an unclassified health care institution; a health care institution class or subclass in A.R.S. Title 36, Chapter 4 or 9 A.A.C. 10; or one of the following classes or subclasses:
 - 1. General hospital.
 - 2. Rural general hospital.
 - 3. Special hospital.
 - 4. Adult day health care facility.
 - 5. Adult foster care.
 - 6. Assisted living center.
 - 7. Assisted living home.
 - 8. Home health agency.
 - 9. Hospice.
 - 10. Hospice inpatient facility.
 - 11. Nursing care institution.
 - 12. Home health agency.
 - 13. Abortion clinic.
 - 14. Recovery care center.
 - 15. Outpatient surgical center, or
 - 16. Outpatient treatment center.
- B.** A health care institution shall comply with the requirements in R9-10-115 if:
 - 1. There are no specific rules in 9 A.A.C. 10 or 9 A.A.C. 20 for the health care institution’s class or subclass, or
 - 2. The Department determines that the health care institution is an unclassified health care institution.

R9-10-103. ~~Reserved~~ Licensure Exceptions

- A.** Except for R9-10-122, this Article does not apply to a behavioral health service agency regulated under 9 A.A.C. 20.
- B.** A health care institution license is required for each health care institution except:
 - 1. A facility exempt from licensure under A.R.S. § 36-402, or
 - 2. A health care institution’s administrative office.
- C.** The Department does not require a separate health care institution license for:
 - 1. An accredited facility of an accredited hospital under A.R.S. § 36-422(F) or (G);
 - 2. A facility operated by a licensed health care institution that is:
 - a. Adjacent to the licensed health care institution; or
 - b. Not adjacent to the licensed health care institution but is connected to the licensed health care institution by an all-weather enclosure and that is:
 - i. Owned by the health care institution, or
 - ii. Leased by the health care institution with exclusive rights of possession; or
 - 3. A mobile clinic operated by a licensed health care institution.

R9-10-104. ~~Reserved~~ Approval of Architectural Plans and Specifications

- A.** For approval of architectural plans and specifications for the construction or modification of a health care institution that is required by this Chapter to comply with any of the physical plant codes and standards incorporated by reference in R9-1-412, an applicant shall submit to the Department an application packet including:
 - 1. An application form provided by the Department that contains:
 - a. For construction of a new health care institution:
 - i. The health care institution’s name, street address, city, state, zip code, telephone number, and fax number;
 - ii. The name and address of the health care institution’s governing authority;
 - iii. The requested health care institution class or subclass; and
 - iv. The requested licensed capacity for the health care institution;
 - b. For modification of a licensed health care institution:
 - i. The health care institution’s license number,
 - ii. The name and address of the licensee,
 - iii. The health care institution’s class or subclass, and
 - iv. The health care institution’s existing licensed capacity and the requested licensed capacity for the health care institution;

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- c. The health care institution's contact person's name, street address, city, state, zip code, telephone number, and fax number;
 - d. If the application includes architectural plans and specifications:
 - i. A statement signed by the governing authority or the licensee that the architectural plans and specifications comply with applicable licensure requirements in A.R.S. Title 36, Article 4 and 9 A.A.C. 10 and the health care institution is ready for an onsite inspection by a Department representative;
 - ii. The project architect's name, street address, city, state, zip code, telephone number, and fax number; and
 - iii. A statement signed and sealed by the project architect, according to the requirements in 4 A.A.C. 30, Article 3, that the project architect has complied with A.A.C. R4-30-301 and the architectural plans and specifications are in substantial compliance with applicable licensure requirements in A.R.S. Title 36, Article 4 and 9 A.A.C. 10;
 - e. A narrative description of the project; and
 - f. If providing or planning to provide medical services, which require compliance with specific physical plant codes and standards incorporated by reference in R9-1-412, the number of rooms or inpatient beds designated for providing the medical services;
2. If the health care institution is located on land under the jurisdiction of a local governmental agency, one of the following:
- a. A building permit for the construction or modification issued by the local governmental agency; or
 - b. If a building permit issued by the local governmental agency is not required, zoning clearance issued by the local governmental agency that includes:
 - i. The health care institution's name, street address, city, state, zip code, and county;
 - ii. The health care institution's class or subclass and each type of medical services to be provided; and
 - iii. A statement signed by a representative of the local governmental agency stating that the address listed is zoned for the health care institution's class or subclass;
3. The following information on architectural plans and specifications that is necessary to demonstrate that the project described on the application form complies with applicable codes and standards incorporated by reference in R9-1-412:
- a. A table of contents containing:
 - i. The architectural plans and specifications submitted,
 - ii. The physical plant codes and standards incorporated by reference in R9-1-412 that apply to the project or are required by a local governmental agency,
 - iii. An index of the abbreviations and symbols used in the architectural plans and specifications, and
 - iv. The facility's specific International Building Code construction type and International Building Code occupancy type;
 - b. If the facility is larger than 3,000 square feet and is or will be occupied by more than 20 individuals, the seal of an architect on the architectural plans and drawings according to the requirements in A.R.S. Title 32, Chapter 1;
 - c. A site plan, drawn to scale, of the entire premises showing streets, property lines, facilities, parking areas, outdoor areas, fences, swimming pools, fire access roads, fire hydrants, and access to water mains;
 - d. For each facility, on architectural plans and specifications:
 - i. A floor plan, drawn to scale, for each level of the facility, showing the layout and dimensions of each room, the name and function of each room, means of egress, and natural and artificial lighting sources;
 - ii. A diagram of a section of the facility, drawn to scale, showing the vertical cross-section view from foundation to roof and specifying construction materials;
 - iii. Building elevations, drawn to scale, showing the outside appearance of each facility;
 - iv. The materials used for ceilings, walls, and floors;
 - v. The location, size, and fire rating of each door and each window and the materials and hardware used, including safety features such as fire exit door hardware and fireproofing materials;
 - vi. A ceiling plan, drawn to scale, showing the layout of each light fixture, each fire protection device, and each element of the mechanical ventilation system;
 - vii. An electrical floor plan, drawn to scale, showing the wiring diagram and the layout of each lighting fixture, each outlet, each switch, each electrical panel, and electrical equipment;
 - viii. A mechanical floor plan, drawn to scale, showing the layout of heating, ventilation, and air conditioning systems;
 - ix. A plumbing floor plan, drawn to scale, showing the layout and materials used for water and sewer systems including the water supply and plumbing fixtures;
 - x. A floor plan, drawn to scale, showing the communication system within the health care institution including the nurse call system, if applicable;
 - xi. A floor plan, drawn to scale, showing the automatic fire extinguishing, fire detection, and fire alarm systems; and

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- xii. Technical specifications describing installation and materials used in the health care institution;
- 4. The estimated total project cost including the costs of:
 - a. Site acquisition.
 - b. General construction.
 - c. Architect fees.
 - d. Fixed equipment, and
 - e. Movable equipment;
- 5. The following, as applicable:
 - a. If the health care institution is located on land under the jurisdiction of a local governmental agency, one of the following provided by the local governmental agency:
 - i. A copy of the Certificate of Occupancy.
 - ii. Documentation that the facility was approved for occupancy, or
 - iii. Documentation that a certificate of occupancy for the facility is not available;
 - b. A certification and a statement that the construction or modification of the facility is in substantial compliance with applicable licensure requirements in A.R.S. Title 36, Article 4 and 9 A.A.C. 10 signed by the project architect, the contractor, and the owner;
 - c. A written description of any work necessary to complete the construction or modification submitted by the project architect;
 - d. If the construction or modification affects the health care institution's fire alarm system, a contractor certification and description of the fire alarm system on a form provided by the Department;
 - e. If the construction or modification affects the health care institution's automatic fire extinguishing system, a contractor certification of the automatic fire extinguishing system on a form provided by the Department;
 - f. If the construction or modification affects the health care institution's heating, ventilation, or air conditioning, a copy of the heating, ventilation, air conditioning, and air balance tests and a contractor certification of the heating, ventilation, or air conditioning systems;
 - g. If draperies, cubicle curtains, or floor coverings are installed or replaced, a copy of the manufacturer's certification of flame spread for the draperies, cubicle curtains, or floor coverings;
 - h. For a health care institution using inhalation anesthetics or nonflammable medical gas, a copy of the Compliance Certification for Inhalation Anesthetics or Nonflammable Medical Gas System required in the National Fire Codes incorporated by reference in R9-1-412;
 - i. If a generator is installed, a copy of the installation acceptance required in the National Fire Codes incorporated by reference in R9-1-412;
 - j. For a health care institution providing radiology, a written report from a certified health physicist of the location, type, and amount of radiation protection; and
 - k. If a factory-built building is used by a health care institution:
 - i. A copy of the installation permit and the copy of a certificate of occupancy for the factory-built building from the Office of Manufactured Housing; or
 - ii. A written report from an individual registered as an architect or a professional structural engineer under 4 A.A.C. 30, Article 2, stating that the factory-built building complies with applicable design standards;
- 6. A statement signed by the project architect that final architectural drawings and specifications have been submitted to the person applying for a health care institution license or the licensee of the health care institution; and
- 7. The applicable fee required by R9-10-122.
- B.** Before an applicant submits an application for approval of architectural plans and specifications for the construction or modification of a health care institution, an applicant may request an architectural evaluation by submitting the documents in subsection (A)(3) to the Department.
- C.** The Department shall approve or deny an application for approval of architectural plans and specifications of a health care institution in this Section according to R9-10-108.
- D.** In addition to obtaining an approval of a health care institution's architectural plans and specifications, a person shall obtain a health care institution license before operating the health care institution.

R9-10-105. Reserved Initial License Application

- A.** A person applying for a health care institution license shall submit to the Department an application packet that contains:
 - 1. An application form provided by the Department including:
 - a. The health care institution's:
 - i. Name, street address, mailing address, telephone number, fax number, and e-mail address;
 - ii. Tax ID number; and
 - iii. Class or subclass listed in R9-10-102 for which licensure is requested;
 - b. Except for a home health agency or a hospice, whether the health care institution is located within 1/4 mile of agricultural land;
 - c. Whether the health care institution is located in a leased facility;

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- d. Whether the health care institution is ready for a licensing inspection by the Department;
 - e. If the health care institution is not ready for a licensing inspection by the Department, the date the health care institution will be ready for a licensing inspection;
 - f. Owner information including:
 - i. The owner's name, address, telephone number, and fax number;
 - ii. Whether the owner is a sole proprietorship, a corporation, a partnership, a limited liability partnership, a limited liability company, or a governmental agency;
 - iii. If the owner is a partnership or a limited liability partnership, the name of each partner;
 - iv. If the owner is a limited liability company, the name of the designated manager or, if no manager is designated, the names of any two members of the limited liability company;
 - v. If the owner is a corporation, the name and title of each corporate officer;
 - vi. If the owner is a governmental agency, the name and title of the individual in charge of the governmental agency or the name of an individual in charge of the health care institution designated in writing by the individual in charge of the governmental agency;
 - vii. Whether the owner or any person with 10% or more business interest in the health care institution has had a license to operate a health care institution denied, revoked, or suspended; the reason for the denial, suspension, or revocation; the date of the denial, suspension, or revocation; and the name and address of the licensing agency that denied, suspended, or revoked the license;
 - viii. Whether the owner or any person with 10% or more business interest in the health care institution has had a health care professional license or certificate denied, revoked, or suspended; the reason for the denial, suspension, or revocation; the date of the denial, suspension, or revocation; and the name and address of the licensing agency that denied, suspended, or revoked the license or certificate; and
 - ix. The name, title, address, and telephone number of the owner's statutory agent or the individual designated by the owner to accept service of process and subpoenas;
 - g. The name and address of the governing authority;
 - h. The chief administrative officer's:
 - i. Name,
 - ii. Title,
 - iii. Highest educational degree, and
 - iv. Work experience related to the health care institution class or subclass for which licensure is requested; and
 - i. Signature required in A.R.S. § 36-422(B) that is notarized;
2. If the health care institution is located in a leased facility, a copy of the lease showing the rights and responsibilities of the parties and exclusive rights of possession of the leased facility;
 3. If applicable, a copy of the owner's articles of incorporation, partnership or joint venture documents, or limited liability documents;
 4. If applicable, the name and address of each owner or lessee of any agricultural land regulated under A.R.S. § 3-365 and a copy of the written agreement between the applicant and the owner or lessee of agricultural land as prescribed in A.R.S. § 36-421(D);
 5. Except for a home health agency or a hospice, one of the following:
 - a. If the health care institution is required by this Chapter to comply with any of the physical plant codes and standards incorporated by reference in R9-1-412, documentation of the health care institution's architectural plans and specifications approval in R9-10-104; or
 - b. If the health care institution is not required by this Chapter to comply with any of the physical plant codes and standards incorporated by reference in R9-1-412:
 - i. Documentation from the local jurisdiction of compliance with all applicable local building codes and zoning ordinances;
 - ii. The licensed capacity requested by the applicant for the health care institution;
 - iii. A site plan showing each facility, the property lines of the health care institution, each street and walkway adjacent to the health care institution, parking for the health care institution, fencing and each gate on the health care premises, and, if applicable, each swimming pool on the health care premises; and
 - iv. A floor plan showing, for each story of a facility, the room layout, room usage, each door and each window, plumbing fixtures, each exit, and the location of each fire protection device; and
 6. The applicable application fee required by R9-10-122.
- B.** In addition to the initial application requirements in this Section, an applicant shall comply with the initial application requirements in specific rules in 9 A.A.C. 10 for the health care institution class or subclass for which licensure is requested.
- C.** The Department shall approve or deny an application in this Section according to R9-10-108.

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R9-10-107. ~~Reserved~~ Renewal License

- A.** A licensee applying to renew a health care institution license shall submit an application packet to the Department at least 60 days but not more than 120 days before the expiration date of the current license that contains:
1. A renewal application on a form provided by the Department including:
 - a. The health care institution's:
 - i. Name, license number, mailing address, telephone number, fax number, and e-mail address; and
 - ii. Class or subclass;
 - b. Owner information including:
 - i. The owner's name, address, telephone number, and fax number;
 - ii. Whether the owner is a sole proprietorship, a corporation, a partnership, a limited liability partnership, a limited liability company, or a governmental agency;
 - iii. If the owner is a partnership or a limited liability partnership, the name of each partner;
 - iv. If the owner is a limited liability company, the name of the designated manager or, if no manager is designated, the names of any two members of the limited liability company;
 - v. If the owner is a corporation, the name and title of each corporate officer;
 - vi. If the owner is a governmental agency, the name and title of the individual in charge of the governmental agency or the individual designated in writing by the individual in charge of the governmental agency;
 - vii. Whether the owner or any person with 10% or more business interest in the health care institution has had a license to operate a health care institution denied, revoked, or suspended since the previous license application was submitted; the reason for the denial, suspension, or revocation; the date of the denial, suspension, or revocation; and the name and address of the licensing agency that denied, suspended, or revoked the license;
 - viii. Whether the owner or any person with 10% or more business interest in the health care institution has had a health care professional license or certificate denied, revoked, or suspended since the previous license application was submitted; the reason for the denial, suspension, or revocation; the date of the denial, suspension, or revocation; and the name and address of the licensing agency that denied, suspended, or revoked the license or certificate; and
 - ix. The name, title, address, and telephone number of the owner's statutory agent or the individual designated by the owner to accept service of process and subpoenas;
 - c. The name and address of the governing authority;
 - d. The chief administrative officer's:
 - i. Name.
 - ii. Title.
 - iii. Highest educational degree, and
 - iv. Work experience related to the health care institution class or subclass for which licensure is requested; and
 - e. Signature required in A.R.S. § 36-422(B) that is notarized;
 2. If the health care institution is located in a leased facility, a copy of the lease showing the rights and responsibilities of the parties and exclusive rights of possession of the leased facility; and
 3. The applicable renewal application and licensure fees required by R9-10-122.
- B.** In addition to the renewal application requirements in this Section, a licensee shall comply with the renewal application requirements in specific rules in 9 A.A.C. 10 or 9 A.A.C. 20 for the health care institution's class or subclass.
- C.** If a licensee submits a health care institution's current accreditation report from a nationally recognized accrediting organization, the Department shall not conduct an onsite inspection of the health care institution as part of the substantive review for a renewal license.
- D.** The Department shall approve or deny a renewal license according to R9-10-108.
- E.** The Department shall issue a renewal license for:
1. One year, if a licensee is in substantial compliance with the applicable statutes and this Chapter, and the licensee agrees to implement a plan acceptable to the Department to eliminate any deficiencies;
 2. Two years, if a licensee has no deficiencies at the time of the Department's licensure inspection; or
 3. The duration of the accreditation period, if:
 - a. A licensee's health care institution is a hospital accredited by a nationally recognized accreditation organization, and
 - b. The licensee submits a copy of the hospital's accreditation report.

R9-10-108. ~~Reserved~~ Time-frames

- A.** The overall time-frame for each type of approval granted by the Department is listed in Table 1. The applicant and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. The substantive review time-frame and the overall time-frame may not be extended by more than 25% of the overall time-frame.

- B.** The administrative completeness review time-frame for each type of approval granted by the Department as prescribed in this Article is listed in Table 1. The administrative completeness review time-frame begins on the date the Department receives a complete application packet or a written request for a change in a health care institution license according to R9-10-109(E):
1. The application packet for an initial health care institution license is not complete until the applicant provides the Department with written notice that the health care institution is ready for a licensing inspection by the Department.
 2. If the application packet or written request is incomplete, the Department shall provide a written notice to the applicant specifying the missing document or incomplete information. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the date the Department receives the missing document or information from the applicant.
 3. When an application packet or written request is complete, the Department shall provide a written notice of administrative completeness to the applicant.
 4. For an initial health care institution application, the Department shall consider the application withdrawn if the applicant fails to supply the missing documents or information included in the notice described in subsection (B)(2) within 180 days from the date of the notice described in subsection (B)(2).
 5. If the Department issues a license or grants an approval during the time provided to assess administrative completeness, the Department shall not issue a separate written notice of administrative completeness.
- C.** The substantive review time-frame is listed in Table 1 and begins on the date of the notice of administrative completeness.
1. The Department may conduct an onsite inspection of the facility:
 - a. As part of the substantive review for approval of architectural plans and specifications;
 - b. As part of the substantive review for issuing a health care institution initial or renewal license; or
 - c. As part of the substantive review for approving a change in a health care institution's license.
 2. During the substantive review time-frame, the Department may make one comprehensive written request for additional information or documentation. If the Department and the applicant agree in writing, the Department may make supplemental requests for additional information or documentation. The time-frame for the Department to complete the substantive review is suspended from the date of a written request for additional information or documentation until the Department receives the additional information or documentation.
 3. The Department shall send a written notice of approval or a license to an applicant who is in substantial compliance with applicable requirements in A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10.
 4. After an applicant for an initial health care institution license receives the written notice of approval in subsection (C)(3), the applicant shall submit the applicable license fee in R9-10-122 to the Department within 60 days of the date of the written notice of approval.
 5. The Department shall provide a written notice of denial that complies with A.R.S. § 41-1076 to an applicant who does not:
 - a. For an initial health care institution application, submit the information or documentation in subsection (C)(2) within 120 days of the Department's written request to the applicant;
 - b. Comply with the applicable requirements in A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10; or
 - c. Submit the fee required in R9-10-122.
 6. An applicant may file a written notice of appeal with the Department within 30 days after receiving the notice described in subsection (C)(5). The appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.
 7. If a time-frame's last day falls on a Saturday, a Sunday, or an official state holiday, the Department shall consider the next business day to be the time-frame's last day.

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TABLE 1

<u>Type of Approval</u>	<u>Statutory Authority</u>	<u>Overall Time-frame</u>	<u>Administrative Completeness Time-frame</u>	<u>Substantive Review Time-frame</u>
<u>Approval of architectural plans and specifications R9-10-104</u>	<u>A.R.S. §§ 36-405, 36-406(1)(b), and 36-421</u>	<u>105 days</u>	<u>45 days</u>	<u>60 days</u>
<u>Health care institution initial license R9-10-105</u>	<u>A.R.S. §§ 36-405, 36-407, 36-421, 36-422, 36-424, and 36-425</u>	<u>120 days</u>	<u>30 days</u>	<u>90 days</u>
<u>Health care institution renewal license R9-10-107</u>	<u>A.R.S. §§ 36-405, 36-407, 36-422, 36-424, and 36-425</u>	<u>120 days</u>	<u>30 days</u>	<u>90 days</u>
<u>Approval of a change to a health care institution license R9-10-109(E)</u>	<u>A.R.S. §§ 36-405, 36-407, and 36-422</u>	<u>75 days</u>	<u>15days</u>	<u>60 days</u>

R9-10-109. Reserved Changes Affecting a License

- A.** A licensee shall ensure that the Department is notified in writing at least 30 days before the effective date of:
1. A change in the name of:
 - a. A health care institution, or
 - b. The licensee; or
 2. A change in the address of a health care institution that does not provide medical services, nursing services, or health-related services on the premises.
- B.** A licensee of a health care institution that is required by this Chapter to comply with any of the physical plant codes and standards incorporated by reference in R9-1-412 shall submit an application for approval of architectural plans and specifications for a modification of the health care institution.
- C.** A governing authority shall submit a license application required in R9-10-105 for:
1. A change in ownership of a health care institution;
 2. A change in the address or location of a health care institution that provides medical services, nursing services, or health-related services on the premises; or
 3. A change in a health care institution's class or subclass.
- D.** A governing authority is not required to submit documentation of a health care institution's architectural plans and specifications required in R9-10-105(A)(5) if:
1. The health care institution has not ceased operations for more than 30 days,
 2. A modification has not been made to the health care institution,
 3. The services the health care institution is authorized by the Department to provide are not changed, and
 4. The location of the health care institution's premises is not changed.
- E.** A licensee of a health care institution that is not required to comply with the physical plant codes and standards incorporated by reference in R9-1-412 shall submit a written request for a change in the services the health care institution is authorized by the Department to provide or a modification of the health care institution including documentation of compliance with requirements in this Chapter for the change or the modification that contains:
1. The health care institution's name, address, and license number;
 2. A narrative description of the change or modification;
 3. The governing authority's name and dated signature; and
 4. Any documentation that demonstrates that the requested change or modification complies with applicable requirements in this Chapter.
- F.** The Department shall approve or deny a request for a change or modification in this Section according to R9-10-108.
- G.** A licensee shall not implement a change or modification described in this Section until an amended license or a new license is issued by the Department.

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R9-10-110. ~~Reserved Enforcement Actions~~

A. If the Department determines that an applicant or licensee is not in substantial compliance with applicable laws and rules, the Department may:

1. Issue a provisional license to the applicant or licensee under A.R.S. § 36-425.
2. Assess a civil penalty under A.R.S. § 36-431.01.
3. Impose an intermediate sanction under A.R.S. § 36-427.
4. Remove a licensee and appoint another person to continue operation of the health care institution pending further action under A.R.S. § 36-429.
5. Suspend or revoke a license under R9-10-111 and A.R.S. § 36-427.
6. Deny a license under R9-10-111, or
7. Issue an injunction under A.R.S. § 36-430.

B. In determining which action in subsection (A) is appropriate, the Department shall consider the threat to the health, safety, and welfare of patients in the health care institution based on:

1. Repeated violations of statutes or rules.
2. Pattern of non-compliance.
3. Types of violation.
4. Severity of violation, and
5. Number of violations.

R9-10-111. ~~Legal authority Denial, Revocation, or Suspension of License~~

~~The Arizona State Department of Health, pursuant to the authority granted in Title 36, Chapter 4 and pertinent paragraphs of A.R.S. § 36-136(G) adopts the rules, regulations and standards contained in Chapter 10 for the licensing and regulation of health care institutions.~~

~~The Department may deny, revoke, or suspend a license to operate a health care institution if an applicant, a licensee, or a person with a business interest of 10% or more in the health care institution:~~

1. ~~Provides false or misleading information to the Department;~~
2. ~~Has had in any state or jurisdiction any of the following:~~
 - a. ~~An application or license to operate a health care institution denied, suspended, or revoked, unless the denial was based on failure to complete the licensing process within a required time-frame; or~~
 - b. ~~A health care professional license or certificate denied, revoked, or suspended; or~~
3. ~~Has operated a health care institution, within the ten years preceding the date of the license application, in violation of A.R.S. Title 36, Chapter 4 or this Chapter, endangering the health and safety of patients.~~

R9-10-112. ~~Intent and purpose of this Article Repealed~~

~~**A.** Health care institutions provide services ranging from medical and specialized care to health related services only. The units within this institutional spectrum are classified in R9-10-114 in accordance with the range and depth of services and care, the qualifications of staff and the physical plant and equipment. Classification of patients among the classes or subclasses of health care institutions is determined by the care needed by the patient. In institutions other than general hospitals, it is the responsibility of the governing body and the administrator to accept only those patients whose needs do not exceed the specialty or range of services for which the institution is licensed.~~

~~**B.** It is the objective of the Director, in the adoption of the regulations in this Chapter:~~

1. ~~To provide each institution latitude for maximum utilization of medical and paramedical manpower and the sharing of central services to the extent consistent with good health care and to encourage all institutions to use inter-institutional and outside service agreements, where appropriate, in lieu of unnecessary duplication of services at each facility;~~
2. ~~To establish minimum standards for personnel, facilities, services, policies, procedures and records;~~
3. ~~To assure that each patient is placed in an institution qualified to provide the care his needs may require;~~
4. ~~To promote the establishment of innovative methods and activities to reduce the cost and improve the quality of health care. To that end, the Department intends to temper the uniform application of regulations in this Chapter with intelligent discretion. It is not intended that the application of this subsection would permit the relaxation of standards, but rather, the use of alternate methods for efficiently achieving equal or higher standards.~~

R9-10-113. ~~Definitions Repealed~~

~~**A.** Words defined in A.R.S. § 36-401 have the same meaning when used in this Chapter except “residential care institution”, “supervisory care services”, and “facilities which are otherwise defined in subsection (B). The following statutory definitions are noted:~~

1. ~~“Adaptive services” means medical services provided on an outpatient basis.~~
2. ~~“Ambulatory person” means any individual, including one who uses a cane or other ambulatory support device, who is physically and mentally capable under emergency conditions of finding a way to safety without assistance.~~
3. ~~“Construction” means the building, erection, fabrication, or installation of a health care institution or facilities therefor.~~

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4. "Department" means the Department of Health Services.
 5. "Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.
 6. "Director" means the Director of the Department of Health Services.
 7. "Governing authority" means the individual, agency, group or corporation, appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the health care institution is vested.
 8. "Health care institution" means every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, health related services or supervisory care services.
 9. "Health related services" means services, other than medical, pertaining to general supervision, protective, preventive and personal care services or supervisory care services.
 10. "Inpatient beds" or "resident beds" means accommodations, with supporting services such as food, laundry and housekeeping, for patients or residents who generally stay in excess of 24 hours.
 11. "Medical services" means the services pertaining to medical care that are performed at the direction of a physician in behalf of patients by physicians, dentists, nurses and other professional and technical personnel.
 12. "Modification" means the substantial improvement, enlargement, reduction, moving or alteration of, addition to, or other change in a health care institution or its facilities or in the services provided by such an institution.
 13. "Nursing care institution" means a health care institution providing inpatient beds or resident beds and nursing services to persons who need nursing services on a continuing basis but who do not require hospital care or direct daily care from a physician.
 14. "Physician" means any person licensed under provisions of A.R.S. Title 32, Chapter 13 or 17.
 15. "Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.
 16. "Supervisory care home" means a residential care institution, which provides only supervisory care services to more than 5 ambulatory persons unrelated to the administrator or owner of such home.
- B.** In this Chapter, unless the context otherwise requires:
1. "Ancillary nursing personnel" means persons employed to assist registered nurses or licensed practical nurses in the care of patients. This term does not include clerical personnel or volunteers.
 2. "Audiologist" means a person who has been granted a Certificate of Clinical Competence in audiology by the American Speech and Hearing Association, or who has completed the equivalent educational requirements and work experience necessary for such a certificate, or who has completed the academic program and is in the process of accumulating the supervised work experience required to qualify for such a certificate.
 3. "Behavioral health service" means screening, evaluation, care or treatment services to prevent, reduce, or eliminate substance abuse and the behavioral disorders related to 1 or more mental or emotional problems or to substance abuse.
 4. "Behavioral health service agency" means a class of health care institution other than a hospital which provides screening, evaluation, care or treatment to persons having behavioral disorders related to a mental or emotional problem(s) or substance abuse.
 5. "Dietitian" means a person who meets the standards of qualifications established by the Commission on Dietetic Registration under the requirements in effect on or prior to March 9, 1976, or who has completed the academic program and is in the process of accumulating the supervised work experience required to qualify for such registration.
 6. "Director of nursing" means a registered nurse with supervisory and administrative ability who is responsible to the chief administrative officer for direction of nursing service for the entire facility for all shifts.
 7. "Drug administration" means the giving of a single dose of medication to a specific patient as a result of an order of a physician or other authorized medical practitioner.
 8. "Drug dispensing" means the issuing of 1 or more doses of a medication in a suitable container with appropriate label for subsequent administration to or use by a patient.
 9. "Emergency treatment clinic" is a subclass of outpatient treatment center with facilities and limited hospital services for the physical evaluation of outpatients and having as its principal service the initial care of injuries or illnesses.
 10. "Facilities", except where used in the name of a class or subclass is synonymous with health care institution as defined in A.R.S. § 36-401 and includes all places, institutions, and services subject to A.R.S. Title 36, Chapter 4, Articles 1 and 2.
 11. "Health services clinic" is a subclass of outpatient treatment center which provides adaptive services and where patients are not kept overnight as bed patients or treated under general anesthesia.
 12. "Hospital services" means the pre-admission, outpatient, inpatient and post-discharge care provided in or by a general hospital, special hospital, rural general hospital or infirmary.
 13. "Infirmary" is a class of health care institution having 30 or fewer inpatient beds and providing limited hospital services to the staff and students of a school, the members of an association or the clients or wards of a public agency.
 14. "Institution", except where used in the name of a class or subclass, is synonymous with health care institution as defined in A.R.S. § 36-401 and includes all places, facilities and services subject to A.R.S. Title 36, Chapter 4, Articles 1 and 2.

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15. "Intermediate care facility" means a subclass of nursing care institution which provides nursing and health-related services to patients as specified in R9-10-913.
16. "Licensed bed" means an individual patient care unit including a bed and related furniture, equipment and space.
17. "Licensed nursing personnel" means registered and licensed practical nurses.
18. "Medical staff" means physicians, dentists and other practitioners of the healing arts who have been granted privileges by agreement with the institution as defined in the institution's medical staff by-laws.
19. "New construction" means new buildings, addition to existing buildings, conversion of existing buildings or portions thereof or portions of buildings under the provisions of A.R.S. Title 32, Chapter 15.
20. "Nurse practitioner" means a registered nurse certified by the Arizona State Board of Nursing to function as a nurse practitioner in the extended role under the provisions of A.R.S. Title 32, Chapter 15.
21. "Nursing unit" means an organized jurisdiction of nursing services such as a nurses' station and related service areas, special care unit, or outpatient clinic.
22. "Occupational therapist" means a person who is registered or is eligible for registration by the American Occupational Therapy Association, or who has completed the equivalent education requirements and work experience necessary for such registration or who has completed the academic program and is in the process of accumulating the supervised work experience required to qualify for such registration.
23. "Outpatient surgical center" is a subclass of outpatient treatment center with facilities and limited hospital services for the diagnosis or treatment of patients by surgery whose recovery, in the concerning opinion of the surgeon and the anesthesiologist, will not require inpatient care.
24. "Outpatient treatment center" is a class of health care institution without inpatient beds which provides medical services for the diagnosis and treatment of persons on an outpatient basis.
25. "Outpatient treatment clinic" is a subclass of outpatient treatment center and is defined in A.R.S. § 36-421.01, as "... a facility or a portion of a facility where practitioners of the healing arts licensed under Title 32 may practice with necessary diagnostic and treatment facilities and where patients are not kept overnight as bed patients or treated under general anesthesia".
26. "Patient" means a person admitted to or receiving care in an institution.
27. "Personal care facility" means a subclass of nursing care institution which provides nursing and health-related services as specified in R9-10-913.
28. "Physician's assistant" means a person certified under the provisions of A.R.S. Title 32, Chapter 25.
29. "Qualified person" when used in connection with an occupation or position, means a person:
 - a. Who is licensed or has certification, registration or other professional recognition, or if there are no such requirements or standards,
 - b. Who has appropriate training, education, or relevant experience and demonstrates through job performance to the satisfaction of the chief administrative officer the ability to perform the required functions.
30. "Residential care institution" means a health care institution other than a hospital or a nursing care institution which provides resident beds and health-related services for persons who do not need inpatient nursing care. Residential care institutions shall not include:
 - a. Facilities for the mentally retarded except that any other class of health care institution in such facility shall be appropriately licensed.
 - b. Penal or correctional facilities maintained and operated by the state or a political subdivision thereof except that any other class of health care institution in such facility shall be appropriately licensed.
 - c. Foster homes or child welfare agencies operated under a permit from the Department of Economic Security except that any other class of health care institution in such facility shall be appropriately licensed.
 - d. A facility owned or rented as a personal residence in which health-related services may incidentally be provided among family members.
31. "Respiratory therapist" means a person registered or eligible for registration by the American Registry of Inhalation Therapist, Inc., and graduated from an American Medical Association approved respiratory care education and training program, or certified or eligible for certification by the Technician Certification Board of the American Association of Respiratory Therapy and practicing under the supervision of a registered or registration eligible respiratory therapist.
32. "Rural general hospital" means a subclass of hospital having 50 or fewer inpatient beds serving an area located not less than 20 surface travel miles distant from another general hospital or rural general hospital and which provides hospital services.
33. "Skilled nursing care facility" means a subclass of nursing care institutions which provides nursing and health-related services to patients as specified in R9-10-913.
34. "Special hospital" means a subclass of hospital which provides hospital services for person having a specialized medical condition, and which limits admission, care and services to patients appropriate to the specialties for which it has qualified for licensure.

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- 35. ~~“Speech therapist” means a person who has been granted the certificate of clinical competence in speech pathology by the American Speech and Hearing Association, or who has completed the equivalent educational requirement and work experience required for such a certificate or who has completed the academic program and is in the process of accumulating the supervised work experience required to qualify for such registration.~~
- 36. ~~“Supervisory care services” means accommodation, board and general supervision, including assistance to persons in the self-administration of prescribed medications. For purposes of this definition, “general supervision” means protective oversight, including daily awareness of resident functioning and continuous needs and functional level assessment, ability to intervene in a crisis situation and supervision in self-administration of medications.~~
- 37. ~~“Treatment” is the medical, surgical or psychiatric management of a patient or procedure for the cure or amelioration of a disease or pathological condition.~~

R9-10-114. Classifications Repealed

A. Health care institutions are classified and subclassified as follows:

- 1. Hospitals
 - a. General hospitals
 - b. Special hospitals
 - c. Rural general hospitals
- 2. Nursing care institutions
 - a. Skilled nursing care facilities
 - b. Intermediate care facilities
 - c. Personal care facilities
- 3. Outpatient treatment centers
 - a. Outpatient surgical centers
 - b. Emergency treatment clinics
 - c. Outpatient treatment clinics
 - d. Health services clinics
- 4. Residential care institutions
 - a. Supervisory care homes
- 5. Home health agencies
- 6. Infirmaries
- 7. Behavioral health service agencies.

B. Any facilities that are clearly health care institutions but do not come within any of the subclasses listed in subsection (A) shall at a minimum meet the requirements of R9-10-115.

C. All health care institutions are subject to the provisions of Chapters 9 and 11 or this Title, except as otherwise specified, and all health care institutions are subject to all of the provisions of this Article and such other Articles in Chapter 10 that may specifically relate to the subclass of institution concerned.

R9-10-116. Documentation Repealed

Where this Chapter requires an institution to have by laws, rules, regulations, policies, procedures, plans, job descriptions, orders, reports, minutes of meetings, records, contracts, agreements, duty schedules, or any similar items, such requirement means written documents which shall be readily available for inspection by the Director or his representative.

R9-10-117. Transfer to another subclass Repealed

A licensed health care institution which seeks to change its license to a class or subclass outside the class in which it is licensed shall comply with all applicable construction standards adopted by reference in A.A.C. R9-1-412. If the change in license is to another subclass of the same licensed class, the requirements of the code adopted by reference in A.A.C. R9-1-412(A) are not applicable except for new construction or when remodeling is contemplated.

R9-10-121. General requirements for licensure Repealed

A. Application for licensure as a health care institution shall be made on an application form provided by the Department. If more than 1 subclass of license is desired for a single structure, separate applications shall be made and the areas to be covered by each license shall be clearly described.

B. Separate licenses are required for facilities maintained on non-contiguous premises except for branch offices of home health agencies and mobile and temporary clinics operated by governmental agencies. Structures for patient care activities on contiguous grounds and under the same ownership may be licensed as a single institution provided that they are not intersected by a public thoroughfare or, if so intersected, are connected by an all-weather enclosure. For the purpose of this regulation, the term “same ownership” may include wither fee or leasehold ownership or a combination thereof.

C. Applications for licensure of leased premises shall contain a copy of the entire lease showing clearly the respective responsibilities of its parties for the maintenance and upkeep of the property and that the applicant has exclusive rights of possession subject only to normal and reasonable right of entry by the landlord.

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- ~~D.~~ Each licensed facility shall be designated by a distinctive name which shall not be changed without written notification to the Department. Upon receiving such notification, the license will be amended.
- ~~E.~~ Persons acquiring a health care institution must obtain a new license at or immediately prior to transfer of ownership of the institution.
- ~~F.~~ Applications shall be signed, in the case of an individual, by the owner of the health care institution, or in the case of a partnership, or a corporation, by 2 of the officers thereof, or in the case of a governmental unit, by the head of the governmental department having jurisdiction thereof. The signature(s) shall be notarized.
- ~~G.~~ The governing body shall maintain in the administrative offices of the facility a current list of names and addresses of all persons or entities having 10% or more of the ownership interest as well as copies of all deeds, leases, land sale contracts or other documents evidencing control or ownership of the real property.

R9-10-123. Initial application Repealed

- ~~A.~~ An initial application shall include supplementary information with the application form and is required whenever 1 of the following pertains:
 - 1. Institutions seeking an original license in a subclass of health care institution or being relicensed following the revocation or suspension of license, or which have been temporarily closed.
 - 2. Institutions which will have a change of ownership beginning with the new license.
- ~~B.~~ In addition to the requirements of A.R.S. §§ 36-422 and 36-436, an initial application shall contain the following information:
 - 1. Completed questionnaires on ownership, physical plant, staff, records and special services.
 - 2. Fire and sanitation inspection reports unless otherwise specified in the Article applicable to its licensure.
 - 3. Additional attachments required for approval of a clinical laboratory operated in conjunction with a health care institution, when applicable.

R9-10-124. Renewal application Repealed

- ~~A.~~ The Department will notify the institution of the need to renew a license approximately 100 days prior to the expiration date of the then current license. Renewal applications shall be submitted on forms furnished by the Department.
- ~~B.~~ In addition to the requirements of A.R.S. §§ 36-422 and 36-436, a renewal application shall contain the following information:
 - 1. Completed questionnaires on ownership and staffing.
 - 2. Fire and sanitation inspection reports unless otherwise specified in the Article applicable to its licensure.
 - 3. Additional attachments required of institutions operating a clinical laboratory in conjunction therewith.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSURE

ARTICLE 1. GENERAL

PREAMBLE

- 1. Sections Affected** **Rulemaking Action**
R9-10-122 Amend
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):**
Authorizing statutes: A.R.S. §§ 36-136(F) and 36-405(C)
Implementing statutes: A.R.S. § 36-405(C)(3)
- 3. The effective date of the rule:**
July 26, 2002
- 4. A list of all previous notices appearing in the Register addressing the proposed rule:**
Notice of Rulemaking Docket Opening: 7 A.A.R. 5447, December 7, 2001
Notice of Proposed Rulemaking: 8 A.A.R. 699, February 22, 2002

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5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Kathleen Phillips, Rules Administrator

Address: Department of Health Services
1740 W. Adams, Suite 102
Phoenix, AZ 85007

Telephone: (602) 542-1264

Fax: (602) 364-1150

E-mail: kphilli@hs.state.az.us

or

Name: Mary Wiley, Assistant Director

Address: Department of Health Services
Assurance and Licensure Services
1647 E. Morten, Suite 220
Phoenix, AZ 85020

Telephone: (602) 674-4200

Fax: (602) 861-0645

E-mail: mwiley@hs.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rule implements A.R.S. § 36-405(C)(3), which requires the Department of Health Services (Department) to establish and collect an initial license and renewal license free from a health care institution. A.R.S. § 36-405(C)(3) establishes a range of initial license and renewal license fees that shall be collected by the Department. The Department has determined that a rule is necessary to establish the exact fee, within the range established in statute, that will be collected. The rule establishes the exact initial license and renewal license fee that the Department will collect from a health care institution.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rule will impose initial one-time substantial costs upon the Department of approximately \$24,537.00 and annual ongoing moderate costs upon the Department of approximately \$8,976.00. The initial one-time costs include those for notifying health care institutions of the license fees, purchasing four computer work stations, updating the Department's database, and training staff in the collection and processing of initial license and renewal license fees. Annual ongoing costs include those for collecting and processing approximately 3,363 initial license and renewal license fees each year. Through the State General Fund, the Department is allotted 37.5 full-time employees in four licensing programs to inspect, license, and regulate approximately 3,293 health care institutions in Arizona, at an annual cost of approximately \$2,030,609.00.

The rule will impose an annual cost of less than \$1,000.00 upon approximately 87% of Arizona's 3293 licensed health care institutions. Approximately 13%, or 253, of Arizona's health care institutions will experience an annual cost greater than \$1,000.00, with the highest annual cost for a health care institution to renew a health care institution license being \$3,620.00.

The rule should not impose a cost or benefit to a political subdivision.

The rule may impose a cost upon consumers if the initial license and renewal license fees borne by health care institutions are passed along to consumers as higher health care costs.

While the rule imposes substantial initial costs and moderate ongoing costs upon the Department and minimal to moderate costs upon businesses that operate health care institutions, it is not anticipated that the costs to the Department or to businesses will result in an impact to private or public employment.

The cost of the rule to small businesses that operate health care institutions may be different than the cost to other businesses that operate health care institutions, because the license fee is related to the licensed capacity of the health

care institution and because the frequency of payment depends on whether the health care institution receives a one year, two year, or three year license.

The rule will increase state revenues by approximately \$846,903.00 each year.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The Department has made technical and grammatical changes to the rules based on comments received from the Governor's Regulatory Review Council's staff.

11. A summary of the principal comments and the agency response to them:

Oral proceedings were held on the rulemaking on April 3, 2002 in Tucson, on April 4, 2002 in Phoenix, and on April 5, 2002 in Flagstaff. During the comment period of December 7, 2001 to April 5, 2002, eight oral and eight written comments were received. One of the written comments was signed by individuals from 15 different facilities. All commentators expressed opposition to the rule for reasons that include the following:

- a. The nursing home industry is currently experiencing difficult times. Inadequate payment by the Arizona Long Term Care System (ALTCSS) does not even cover the cost of care. There have been several closures of nursing home facilities in low socioeconomic areas of Phoenix. There have been some bankruptcies in the industry. The fees will add an additional burden to an industry already in crisis.
- b. Imposition of the fees will impact care and services to elderly and disabled individuals, creating a burden on the individuals and the families of those individuals that ADHS is supposed to protect and defend.
- c. The fees will create a significant hardship for non-profit facilities.
- d. The vast majority of clients in nursing homes are being funded by the Arizona Health Care Cost Containment System (AHCCCS), so one state agency will be charging a fee that will eventually be paid for by another state agency.
- e. The limited number of self-pay clients will bear the entire cost of the new fees, since the industry can only collect increased revenues from them. Other rates of pay are government controlled.
- f. To increase from zero cost for licensure to the maximum fees allowed by statute is a huge increase.
- g. The fees impose a cost without a possible source for increased revenues.
- h. The funds collected should not go into the State General Fund but to ADHS for training, education, and technical advice to providers.
- i. The small providers are disproportionately impacted by the fees.
- j. State funding sources such as the Tobacco Tax Fund are being taken away at the same time new fees are being charged.
- k. The fees burden facilities with multiple part-time sites in rural communities.

Recommendations made include:

- a. Pay a flat license fee.
- b. Charge a fee that is less than the maximum allowed by statute.
- c. Exempt assisted living facilities serving ten or fewer clients.
- d. Exempt non-profit facilities.
- e. Delay implementation of the rule until January 1, 2003, to allow facilities time to budget for the fees.
- f. Discount the fees or cap the fees at a reduced amount for Medicaid-approved facilities.
- g. Change the system rather than increasing fees.
- h. Assess fees based on type of facility.

The Department is sympathetic to the arguments against the rule and to the recommendations made. However, the Department is required by statute to collect licensing fees. The statute establishes the criteria for the Department to use in assessing the fees. The Department has chosen to assess fees at the greatest amount permitted by statute because of the cost to the Department for processing documentation, completing surveys, monitoring compliance, investigating complaints, and taking enforcement actions. In fact, the Department anticipates that it will only collect approximately 42% of the cost to the state for licensing and regulating health care institutions. Statute also dictates that the funds collected be placed in the State General Fund, and the Department is not authorized to do otherwise. For these reasons, the Department has chosen not to change the proposed rule.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

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13. Incorporations by reference and their location in the rules:

Not applicable

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSURE**

ARTICLE 1. GENERAL

Section

R9-10-122. Fees

ARTICLE 1. GENERAL

R9-10-122. Fees

- A.** An applicant who submits to the Department architectural plans and specifications for the construction or modification of a health care institution shall also submit an architectural drawing review fee as follows:
1. Fifty dollars for a project with a cost of less than \$100,000;
 2. One hundred dollars for a project with a cost of \$100,000 but less than \$500,000; or
 3. One hundred fifty dollars for a project with a cost of \$500,000 or more.
- B.** An applicant submitting an initial application or a renewal application for a health care institution license shall submit to the Department an application fee of \$50.00.
- C.** Except as provided in subsection (D) or (E), an applicant submitting an initial application or a renewal application for a health care institution license shall submit to the Department a license fee as follows:
1. For a facility with no licensed capacity, \$100.00;
 2. For a facility with a licensed capacity of one to 59 beds, \$100.00, plus the licensed capacity times \$10.00;
 3. For a facility with a licensed capacity of 60 to 99 beds, \$200.00 plus the licensed capacity times \$10.00;
 4. For a facility with a licensed capacity of 100 to 149 beds, \$300.00, plus the licensed capacity times \$10.00; or
 5. For a facility with a licensed capacity of 150 beds or more, \$500.00, plus the licensed capacity times \$10.00.
- D.** A person who has paid a health care institution license fee for a facility and submits a behavioral health service agency application for the same facility shall submit an application fee but is not required to submit an additional license fee.
- E.** Subsection (C) does not apply to a health care institution operated by a state agency according to state or federal law or to an adult foster care home.
- ~~E.~~ All fees are nonrefundable except as provided in A.R.S. § 41-1077.